

Unleashing Clinical AI: A Market-Driven Pathway for Deployment and Scale

Executive Summary

The AI Medical Services Act is a pro-innovation legislative framework designed to break the "regulatory paralysis" currently stifling healthcare technology. By establishing the AI Augmented & Autonomous Service Provider (AAASP) as a new category of licensed healthcare provider, the Act shifts the focus from regulating software as a static "product" to licensing AI as a dynamic "clinical practice".

This model creates a definitive path toward reimbursement, provides legal certainty for investors, and opens vast "white spaces" for startups to deploy high-autonomy clinical solutions without waiting for multi-year federal device clearances.

1. Breaking the Innovation Bottleneck

Current innovators are trapped between slow federal approvals and unregulated "consumer apps" that lack clinical integration. This Act creates a third "fast-lane":

- **State Practice Authority:** Asserts state sovereignty over the practice of medicine to license AI services as professional clinical entities.
- **The Regulatory Sandbox:** Enables a 2-year provisional period for rapid deployment and real-world data collection under state supervision.
- **The "Shot Clock":** To prevent bureaucratic "pocket vetoes," the Act mandates a 30-day completeness review and a final decision within 90 days.

2. A Path to Scalability & Reimbursement

The Act solves the "Payment Gap" that often forces AI innovation into unsustainable cash-pay models.

- **Mandated Private Coverage:** Directs the Insurance Commissioner to require that private insurers recognize AAASP licenses as valid provider types.

- **The "Federal Firewall":** Establishes a State Provider Identifier (SPI), allowing for state-funded reimbursement without requiring immediate CMS approval—creating a functional state-level market for AI care today.
- **Value-Based Default:** Encourages Value-Based Care (VBC) models, allowing AI to compete on outcomes and cost-efficiency rather than just fee-for-service volume.

3. Investor Certainty & Anti-Protectionism

This framework is designed to protect entrepreneurs from the "turf wars" and regulatory capture of incumbent human professions.

- **Anti-Capture Voting:** Any rule that restricts AI scope of practice requires a two-thirds (2/3) super-majority vote from the Board.
- **Liability Safe Harbor:** Limits non-economic damages for compliant Sandbox participants to encourage market entry while maintaining clear standards for negligence.
- **Complementary to FDA:** Class B reciprocity automatically recognizes FDA-cleared software, ensuring state licensure comes alongside and accelerates the clinical utility of federal approvals.

Bottom Line for Innovators

The AI Medical Services Act turns clinical AI from a "cost center" into a billable service. By defining liability, billing codes, and insurance requirements, we provide the market certainty necessary for investors to deploy significant capital into the next wave of autonomous healthcare infrastructure.

Appendix: Regulatory Framework & Risk Categorization

The Act utilizes a dual-axis approach, combining AI autonomy levels with clinical severity to ensure oversight is proportionate to risk.

Regulatory Reference Table

Determines when a state AAASP License is required versus when a tool is Exempt.

Condition Category	Informational (L0)	Advisory (Suggest)	Supervised Autonomous (L2)	Fully Autonomous (L3)
Preventive	Exempt	Exempt	Exempt (or Modifier L2)*	Modifier L3 Required
Chronic / Non-Critical	Exempt	Exempt	Modifier L2 Required	Modifier L3 Required
Critical & Time-Sensitive	Exempt	Modifier L1 Required	Modifier L2 Required	Modifier L3 Required

**Supervised Autonomous for preventive is exempt unless the licensee will be ordering preventative labs, drugs or devices at which point it will need an L2 modifier. Understanding the Levels of Autonomy & Risk Tiers*

- **Modifier L0 (Informational/Advisory-Exempt):** AI providing data or suggestions for non-critical conditions where human judgment is the primary driver.
- **Modifier L1 (Advisory-Critical):** AI guiding critical/time-sensitive decisions that substitute for independent judgment.
- **Modifier L2 (Supervised Autonomous):** AI authorized to execute clinical actions under human supervision.
- **Modifier L3 (Fully Autonomous):** AI authorized to independently diagnose, treat, or prescribe.

Clinical Risk Tiers:

- **Preventive:** Low-risk interventions for disease prevention or health maintenance.
- **Chronic / Non-Critical:** Management of persistent conditions where delays do not threaten life.
- **Critical & Time-Sensitive:** High-acuity states requiring immediate, life-preserving intervention.

Licensure Categories:

- **Class A (State Clinical Service):** Regulated as a professional service under state authority (e.g., LDT-style services).
- **Class B (Federal Device Reciprocity):** For AI that has achieved FDA clearance/approval (SaMD).
- **Class C (Therapeutic & Support):** For non-diagnostic therapy, coaching, or monitoring based on existing referrals.

Alignment with the FDA Approach

- This framework is "smart" because it adopts the same philosophy of risk-based stratification found in federal device regulation while applying it to clinical practice.
- **Complementary Classification:** Just as the FDA classifies devices (Class I, II, III) based on risk to the patient, this Act classifies the delivery of the service. It does not attempt to re-regulate the software itself if it is already an FDA-approved device (Class B License).
- **Validated Competency:** Like the FDA's requirement for clinical evidence, the Act requires AI models to operate only within their "validated technical specifications" and "intended use case".
- **Post-Market Surveillance:** The Act mandates Annual Performance Reports and "Model Drift" monitoring. This aligns with the FDA's total product life cycle (TPLC) approach, ensuring the AI remains safe after it enters the market.
- **Least Restrictive Means:** The Board is legally mandated to use the least burdensome regulation to address a specific, documented risk, preserving the "pro-innovation" stance while maintaining safety.